

REMARKS/ARGUMENTS

By the amendment herein, claims 1 and 14-17 will be amended, whereby claims 1-19 will remain pending.

The claims have been amended herein to be even more clearly denote the structural formulas, and to remove step language in the method claims. Accordingly, no new matter should be considered to have been introduced in the present amendment.

Reconsideration and allowance of the application are respectfully requested.

Information Disclosure Statement

Applicants express appreciation for the inclusion with the Office Action of initialed copies of the Forms PTO-1449 submitted with the Information Disclosure Statement filed March 29, 2007 whereby the Examiner's consideration of the Information Disclosure Statement and the documents cited therein is of record.

Claim Of Priority

Applicants note that the Office Action does not acknowledge Applicants' claim of foreign priority nor receipt of the certified copy in this national stage application. Applicants therefore request that the Examiner acknowledge the claim of foreign priority and confirmation of receipt of the certified copy in the next communication from the Patent and Trademark Office.

Response To Rejection Under 35 U.S.C. 112, First Paragraph

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In this ground of rejection, the rejection is apparently asserting that the claims contain subject matter that is not described in the specification in a manner that shows that Applicants were in possession of the claimed invention. In particular, the rejection contends that k3 is not adequately defined, and apparently can give values so that the number of “OH” groups is not included in the illustrated compounds. The rejection points to the examples at pages 29-33 of the specification, and contends that these examples do not depict additional “OH” groups therein.

Applicants submit that the rejection is without appropriate basis and should be withdrawn.

As stated in MPEP §2163.02, Rev. 6, September 2007, beginning at 2100-185:

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Additionally, Applicants submit that the Examiner has not met the required burden to show that the inventors did not have possession of the claimed invention. More

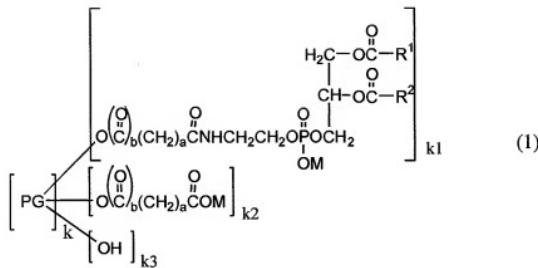
specifically, MPEP 2163.04, Rev. 6, September 2007, page 2100-187 (Burden on the Examiner with Regard to the Written Description Requirement) states:

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

Under the present circumstances, the rejection apparently merely alleges that the Examples do not illustrate every embodiment including formulas that show various "k3" values. However, the question is not whether every "k3" value is shown, but whether the originally filed specification shows that Applicants, at the time of filing of their application, were in possession of the claimed subject matter. Applicants submit that their originally filed disclosure, as well as the state of the art at the time of their invention, establish that they were in possession of the claimed subject matter at the time of the filing of the application.

Applicants submit the specification conveys with reasonable clarity to those skilled in the art that Applicants were in possession of compounds including various k3 values when their application was filed.

Claim 1 is directed to a phospholipid derivative represented by the following formula (1):



wherein $[PG]_k$ represents a residue of polyglycerin having a polymerization degree of k , wherein k is 2 to 50, R^1CO and R^2CO independently represent an acyl group having 8 to 22 carbon atoms, symbol "a" independently represents an integer of 0 to 5, symbol "b" independently represents 0 or 1, M represents hydrogen atom, an alkali metal atom, an ammonium, or an organic ammonium, and k_1 , k_2 , and k_3 represent numbers satisfying the following conditions: $1 \leq k_1 \leq (k+2)/2$, $0 \leq k_2$, and $k_1 + k_2 + k_3 = k + 2$.

Applicants submit that the recited subject matter, including claim 1, and the subject matter further recited in dependent claims 2-19, is fully supported in Applicants' originally filed specification so that one having ordinary skill in the art at the time the application was filed would understand that Applicants were in possession of the claimed subject matter.

For example, attention is directed to Applicants' originally filed application at page 7, beginning in the first full paragraph, wherein the symbols "k1", "k2" and "k3" are defined, as follows:

Symbol "k1" means the number of residues of the phospholipid compound bonded to the residue of polyglycerin, and the number is 1 to $(k+2)/2$. When the number of the bonding residues of phospholipid compound k1 is less than 1, the advantageous effects of the present invention cannot be obtained due to smaller numbers of hydrophobic bond portions in a molecule. Further, when the compound of the present invention is used for a lipid membrane structure, k1 preferably satisfies the condition of $1 \leq k1 \leq 2$. When the number of the bonding residues of phospholipid compound satisfies the condition of $2 < k1 \leq (k+2)/2$, namely, when k1 is more than 2, the residues of the phospholipid compound contained in the compound of the present invention increase, in other words, a lot of hydrophobic portions exist in the molecule. Therefore, the compound becomes more likely to form micelles, and thus the compound can be suitably used as a solubilizer or a dispersing agent.

Symbol "k2" represents the number of groups that bond to the residue of polyglycerin of which end is represented by -COOM, and k2 satisfies the condition of $0 \leq k2$. When k2 is 0, it means that any partial structure, of which end is represented by -COOM, does not substantially exist in the compound of the present invention. Further, when k2 is more than 0, carboxyl groups exist and as a result the compound has polarity. Therefore, the compound can be used for a dispersing agent and the like as an ionic surfactant. When k2 satisfies the condition of $0 \leq k2 \leq 1$, the compound does not unstabilize a lipid membrane structure such as liposome, but can stabilize liposomes due to a small number of carboxyl groups, and therefore the compound can be preferably used. M represents hydrogen atom, an alkali metal atom, an ammonium, or an organic ammonium, preferably hydrogen atom or an alkali metal atom. Specific examples include, for example, an alkali metal atom such as sodium and potassium, an organic ammonium such as triethylammonium and diisopropylammonium, and the like.

Symbol "k3" is the number of the hydroxyl groups that bond to the polyglycerin residue, and the number is an integer satisfying the condition of $k1 + k2 + k3 = k + 2$. The value of $k1 + k2 + k3$ is an integer of 4 to 52, preferably 8 to 52, more preferably 8 to 12. When the value of $k1 + k2 + k3$ is smaller than 4, the advantageous effects of the present invention may not be fully obtained. When the value of $k1 + k2 + k3$ is larger than 52, viscosity of the polyglycerin becomes large, and it may become difficult to obtain such a compound.

Thus, Applicants' originally filed specification provides written description of

symbol "k3" as well as its interrelationship with symbols "k1" and "k2" with respect to polyglycerin compounds according to the disclosed and claimed subject matter.

Therefore, one having ordinary skill in the art would understand that Applicants were in possession of the claimed subject matter at the time of filing their application.

With respect to the examples specifically disclosed in Applicants' specification, Applicants note that, for Examples 1-5, the specifically illustrated examples include representative exemplary compounds wherein $k_1=1$, $k_2=0$, k_3 is respectively 7, 9, 11, 9 and 41, and k is respectively 6, 8, 10, 8 and 40. In particular, according to Examples 1 to 5, distearoylphosphatidylethanolamine as a phospholipid is first reacted with succinic anhydride or glutaric anhydride (Synthesis Examples 1 and 2), and then the resultant is bound with polyglycerin ($k=6, 8, 10, 8$ and 40).

One having ordinary skill in the art following Applicants' originally filed disclosure, including the originally filed examples, would readily understand at the time of filing of Applicants' application that, in these Examples, the values of k_1 and k_3 can be controlled by choosing a molar ratio of phosphatidylethanolamine succinate (or phosphatidylethanolamine glutarate) obtained in Synthesis Example 1 or 2 and polyglycerin to be reacted, and choosing the number of hydroxyl group (hydroxyl value) in the polyglycerin.

Applicants submit that one having ordinary skill in the art would readily understand that Applicants were in possession of the genus of compounds recited in Applicants claims, and would readily understand k_3 values upon review of Applicants' originally filed application, including the originally filed specification.

Accordingly, this ground of rejection is without appropriate basis and should be withdrawn.

Response To Rejection Under 35 U.S.C. 112, Second Paragraph

In response to the rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite, Applicants submit the following.

In this ground of rejection, the Examiner contends that the limitation "k1, k2, and k3 satisfy $8 \leq k1 + k2 + k3 \leq 52$ " lacks antecedent basis in the claim.

In response, Applicants submit the claim 4 is definite. In this regard, claim 1 recites that k is 2 to 50. Therefore, k+2 in claim 1, can be as high as 52. Accordingly, claim 4 is further defining that k1 + k2 + k3 can be as high as 52, and is at least 8.

Applicants request withdrawal of the indefiniteness rejection.

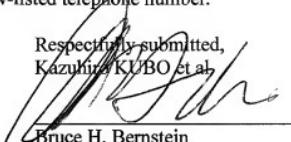
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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